REMARKS

This amendment responds to the Office Action dated May 2, 2006.

In the Office Action on pages 3-8, paragraphs 5-22, the patent examiner rejects all the claims as being non-patentable in view of certain prior art disclosed in the following references:

U.S. Patent No. 4,576,529 to Forrer
U.S. Patent No. 6,193,125 to Grover
U.S. Patent No. 6,743,185 to Weber
U.S. Patent No. 6,074,408 to Freeman

For the record, Applicant does not admit that Grover '125 and Weber '185 are prior art to all aspects of the present invention since Applicant has claimed priority of earlier applications which pre-date those references.

U.S. Patent Nos. 4,576,529 to Forrer and 6,193,125 to Grover relate to hand tool clamp systems and not to "a medical device" as is claimed in the present invention. Forrer '529 is a clamping system for a hand drill (see Abstract, last 4 lines) and Grover '125 is a tool holder for a hand drill. Col. 5, line 23 (herein "5/23"). Forrer '529 and Grover '125 are not relevant art because the medical device operated by the claimed actuator moves the guide wire small distances with respect to the actuator sleeve. The clamp systems and holders of Forrer '529 and Grover '125 permit only gross adjustment and do not, in any manner, relate to the medical use of a guidewire, an actuator sleeve nor a distally located medical device at the end of the guidewire - actuator sleeve combination.

U.S. Patent No. 6,743,185 to Weber (Weber '185) discloses an actuator for a medical device. The endoscopic biopsy instrument 10 has a flexible conduit 12 coupled to a handle assembly 20 and has a pair of jaw-like claws 14 at its distal end.

One or more control members 16 (FIG. 8) extend through the conduit 12 and have

> a proximal end coupled to a movable actuator 22 on the handle assembly 20 and a distal end coupled to the end effectors [claws] 14. For example, distal movement of the actuator 22 could cause movement of the control members 16 in the distal direction to thereby place the ... [claws] in an open position ... and proximal movement of the actuator 22 could cause movement of the control members 16 in the proximal direction to thereby place the end effectors [claws] 14 in a closed position ...

4/13.

The actuator 22 has two sections 23a, 23b, and is shown in FIGs. 1 and 5 - 8. 5/6. "As shown in FIGS. 1, 8, and 9, the handle assembly further includes a reinforcement tube 50 having one or more bends 52a, 52b formed in the tube's proximal end portion." 5/25.

> An interior passage in the tube is sized to accommodate the control members 16. A proximal end of the control members 16 is retained in the reinforcement tube 50 via the reduced cross-sectional area of the reinforcement tube 50 in the region of the bends 52a, 52b.

5/31

Actuator portions 23a, 23b retain reinforcement tube bends 52a, 52b via projection members 54a, 54b. 5/43. see FIG. 8

The conduit 12 (within which travels control wires 16) is engaged or attached to body member 24. 6/1. Operationally, and in reference to FIG. 5, actuator 22 (note actuator parts 23a, 23b, see 5/7) moves in the cut-out 38 of the handle 20 and thereby moves the control wires (locked in reinforcement tube (see FIG. 8)) longitudinally with respect to the fixed conduit 12. Apparently, the reinforcement tube moves with the control wires.

With respect to Freeman '408, the medical device, operative with an endoscope, includes an inner actuator cable 20 slidably disposed in elongated guide member 18. 5/10. "The actuator handle 16 moves the inner actuation cable 20 within the guide member 18 to actuate the head assembly 22, which is used to perform the procedure, e.g. grasping objects, within the patient." 5/16.

The proximal end of the guide member 18 (the outer tube) is attached to the first coupling member 40. 5/45

> The handle actuator 16 [FIG. 1] includes a handle body 26 having a thumb ring 28 coupled at one end of the handle body 26. In one embodiment, a spool sliding member 30 is slideably disposed on the handle body 26. The spool sliding member 30 is coupled to a proximal end 32 of the actuator cable 20, for example, using a clamping mechanism 34. The clamping mechanism 34 preferably includes a cable clamp 36 ... and a thumb screw 38 ... such that the proximal end 32 of the actuation cable 20 is clamped between the cable clamp 36 and the thumb screw 38. Thus, when the spool sliding member 30 slides along the handle body 26 generally in the direction of arrows 35, the actuator cable 20 slides relative to the guide member 18 and actuates, e.g. opens/closes, the instrument head assembly 22, as will be described in greater detail below.

5/24

The Examiner, in the Office Action, indicated that items in the preamble, such as the actuation sleeve (and now the inner tube or wire which runs in the actuation sleeve) is not properly part of the patentablity analysis for the claims. It is respectfully submitted that the MPEP states that structure in the preamble is part of the claim if the item is tied to other structure recited in the body of the claim.

> Any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. See, e.g., *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989) (The determination of whether preamble recitations are structural limitations can be resolved only on review of the entirety of the application "to gain an understanding of what the inventors actually invented and intended to encompass by the claim."); *Pac-Tec Inc. v. Amerace Corp.*, 903 F.2d 796, 801, 14 USPQ2d 1871, 1876 (Fed. Cir. 1990) (determining that preamble language that constitutes a structural limitation is actually part of the claimed invention). See also *In re Stencel*, 828 F.2d 751, 4 USPQ2d 1071 (Fed. Cir. 1987). (The claim at issue was directed to a driver for setting a joint of a threaded collar*>;< however>,< the body of the claim did not directly include the structure of the collar as part of the claimed article. The examiner did not consider the preamble, which did set forth the structure of the collar, as limiting the claim. The court found that the collar structure could not be ignored. While the claim was not directly limited to the collar, the collar structure recited in the preamble did limit the structure of the driver. "[T]he framework - the teachings of the prior art -

against which patentability is measured is not all drivers broadly, but drivers suitable for use in combination with this collar, for the claims are so limited." Id. at 1073, 828 F.2d at 754.).

MPEP § 2111.02(I)

The claims have been amended to recite that the proximal actuator or deployment handle operates a distally located medical device. Further, the preamble of the claims now recite that the actuation sleeve has a movable tube or wire therein. Support for these concepts is found in FIGs. 32 - 35. Each claim now recites either an actuator body with mounted retaining devices or a body with a handle with such retaining devices. See FIGs. 35 - 39.

The claims are patentable because none of the references show, teach or suggest "retaining devices" which are "laterally removably attachable" to either the actuation sleeve or the tube or wire. In some claims, the second section of the actuator sleeve is attached to the tube or wire, thereby making the retaining device laterally attachable to the second section and, by logic, to the tube or wire. As stated in the patent specification: "The proximal actuator of the present invention, when transversely or laterally (not longitudinally) removably mounted on the distal end of the control system, permits the operator to move one wire or tube with respect to the other wire or tube..." para. 135. the key terms herein are (a) removably attachable and (b) laterally removable. "Laterally removably" means that attachment is via transverse, not longitudinal or axial, action with respect to the elongated actuator-sleeve-guidewire combination.

"An important feature of the present invention is that the proximal actuator need not be axially threaded onto or off of the guide wire-actuator sleeve system. The proximal actuator is removably mounted to the tube in a tube or wire over a wire system by transversely or laterally attaching the proximal actuator at a desired location on the guide wire-actuator sleeve.

Thereafter, axial movement of the first and second movable members (that is, the wire within the tube) is achieved by moving the first and second retainer of the proximal actuator away from each other." para. 149.

All the references which deal with medical devices cited by the Examiner, Weber '185 and Freeman '408, require that the actuator-sleeve-guidewire (tube within a tube, para. 18) must be axially threaded or longitudinally inserted into the proximal handle-actuator. In the presently claimed invention, the proximal actuator-handle-retaining device is "laterally removably attachable" to the actuator-sleeve-guidewire system. This enables the surgeon to attach and detach the proximal handle-actuator without longitudinally threading the actuator-sleeve-guide wire system.

Therefore, Applicant respectfully requests that the Examiner withdraw the rejections against claims 1 - 52 and allow the claims.

Respectfully submitted,

By _____/Robert Kain/ _____
Robert C. Kain, Jr.
Reg. No. 30,648
Fleit, Kain, Gibbons, Gutman, Bongini & Bianco, P.L.
750 Southeast Third Avenue, Suite 100
Ft. Lauderdale, FL 33316-1153
Telephone: 954-768-9002
Facsimile: 954-768-0158

Certificate of E-Filing

I hereby certify that this correspondence is being efiled with the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on July 24, 2006.

_____/Robert Kain_____
Robert C. Kain, Jr.
Reg. No. 30,648 H:\RCK\CLIENTS\SCV\2015-37-Amdt-1st-072006.wpd